

REMARKS

This amendment is responsive to the Office Action mailed July 18, 2007. Applicant submits concurrently herewith: (1) a Petition for Extension of Time; and (2) Exhibit A: copies of the Patent and Trademark Office stamped Request for Continued Examination Form, Petition for Extension of Time, and first page of the Amendment under 37 C.F.R. 1.114, filed on June 25, 2007.

Claims 1-15 are pending in the application. In the Office Action mailed July 18, 2007, claims 1-15 have been rejected. In the instant Amendment, claim 9 has been amended to recite "a pharmaceutically acceptable salt, hydrate or salt hydrate thereof." Support for the amendment is found in the specification, e.g., at page 8, paragraph [0037].

No new matter has been added by the amendment. Entry of the foregoing amendment and consideration of the following remarks are respectfully requested.

FILING DATE OF THE LAST RESPONSE

In the Office Action, the Examiner has stated that Applicant's response to the previous office action mailed January 25, 2007 was filed on June 28, 2007 (see, e.g., Office Action Summary). Applicant respectfully submits that papers relating to the response were deposited with the U.S. Postal Service with sufficient postage as first class mail on June 25, 2007. A certificate stating the date of deposit, i.e., June 25, 2007, was included on each documents (copies of the Patent and Trademark Office stamped Request for Continued Examination Form, Petition for Extension of Time, and first page of the Amendment under 37 C.F.R. 1.114 are attached herewith as Exhibit A). Pursuant to 37 C.F.R. 1.8(1), a filing date of June 25, 2007 should be accorded. Applicant respectfully requests that the

filing date be corrected in the record of the present application. Applicant also respectfully requests that a two-month extension fee be charged, and that the fee for the third month of extension, if charged, be refunded to Deposit Account No. 12-1095.

THE DOUBLE-PATENTING REJECTION

Claims 1 and 9-12 have been provisionally rejected as being unpatentable over claims 1, 4-6 and 9 of copending Application No. 10/646,362. This is a provisional obviousness-type double patenting rejection. Applicant respectfully requests that a response to this rejection be deferred until such time when it is the only outstanding issue in the application.

THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 2-3 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in the recitation of "less than about"¹. Applicant respectfully submits that the word "about" is defined in the specification as meaning "approximately" and to modify a numerical value above and below the stated value by a variance of 5% (see, the specification at page 5, paragraph [0022]). Thus, a person skilled in the art would understand the recitation of "less than about." The rejection should therefore be withdrawn.

Claim 9 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the recitation of "a pharmaceutically acceptable derivative thereof." Applicant has amended claim 9 such that the word "derivative" is no longer recited in the claim. The rejection is therefore obviated.

¹ In the Office Action, claim 4 is also included in this rejection. However, claim 4 does not contain the rejected recitation. Therefore, Applicant assumes that claim 4 is included in error.

THE REJECTION UNDER 35 U.S.C. § 103(a)

The Examiner has maintained the rejection of claims 1-15 under 35 U.S.C. § 103(a) as being obvious over Dickinson, et al., WO 99/51205 (hereinafter "*Dickinson*"). The Examiner contends that the difference between *Dickinson* and the claimed invention is that *Dickinson* teaches an aerosol composition while the claimed invention relates to a dry powder. However, the Examiner contends that upon delivery, the composition of *Dickinson* would be in the form of a dry powder, and that it would have been obvious to one ordinary skill in the art that the delivery of dry particle composition to the lungs would be preferable over a liquid composition. The Examiner also contends that particle size distribution is not a patentable distinction absent unexpected results. Applicant respectfully disagrees with the Examiner for reasons set forth below.

First, Applicant respectfully submits that the differences between *Dickinson* and the claimed invention are not limited to an aerosol composition vs. a dry powder. Nonetheless, neither of the reasons offered by the Examiner would have led a person skilled in the art to modify *Dickinson*'s aerosol composition to arrive at the presently claimed dry powder composition. The Examiner's contention, i.e., that upon evaporation of the propellant, the composition of *Dickinson* would be in the form of a dry powder is unsupported and amounts to mere speculation. However, even assuming that such a composition were a "dry powder," it would be distinct from the dry powder inhalation composition as claimed in the present application. The specification of the present application teaches that in the presently claimed dry powder inhalation composition the active ingredient and the carriers are blended (see, e.g., the instant specification at page 9, paragraphs [0046]) and form association

with each other (see, e.g., the instant specification at page 9, paragraphs [0041]). The claimed dry powder inhalation composition is, *inter alia*, suitable for administration by a dry powder inhaler, and "readily filled into the reservoir of a multidose dry powder inhaler" (see, e.g., the instant specification at page 3, paragraphs [0007] and [0008]). It is known in the art that proper association of micronized active ingredient with larger carriers confers the desirable flow and deposition characteristics to a dry powder inhalation composition when dispensed by a dry powder inhaler (see, e.g., the instant specification at page 1, paragraphs [0003], last 6 lines). In contrast, in the "dry powder" of *Dickinson* produced as a result of propellant vaporization, the active ingredient is separated from the carrier by forces generated by the vaporization of the propellant (see, e.g., *Dickinson* at page 8, lines 10-12). A person skilled in the art would have understood that such a "dry powder" would not have the flow and deposition characteristics of the presently claimed dry powder composition. Thus, a person skilled in the art would not have been led by *Dickinson's* "dry powder" to the presently claimed invention.

In response to the Examiner's determination that it would have been obvious to one of ordinary skill in the art that the delivery of dry particle composition to the lungs would be preferable over a liquid composition, Applicant respectfully points out that *Dickinson* clearly teaches that its aerosol composition is for delivery of medicament particles to the lung, not for delivery of a liquid composition (see, e.g., *Dickinson* at page 8, lines 5-13). As discussed above, the Examiner has contended that upon delivery, the composition of *Dickinson* would be in the form of a "dry powder." Thus, even if a person skilled in the art would have known that the delivery of dry particle composition to the lungs would be preferable over a

liquid composition, he/she would have understood that *Dickinson's* aerosol composition has already achieved what is preferable without been modified into the dry powder composition claimed in the present application. Therefore, neither reasons offered by the Examiner would have led a person skilled in the art to the presently claimed invention.

In response to the Examiner's allegation that particle size distribution is not a patentable distinction absent unexpected results, Applicant respectfully points out that the Examiner has the initial burden to establish by evidence that the particle size distribution as recited in the present claims, e.g., carriers having both a VMD of between about 70 and about 120 microns, and a certain proportion of lactose particles of less than 5 microns in diameter, e.g., up to 25% (claim 1), between 6.5 and 24.5% (claim 7), and 8.0-24% (claim 13), is not a patentable distinction. In fact, *Dickinson* teaches selecting the size of its particles based *inter alia* on the solubility of the particles in the liquid propellant (See, e.g., *Dickinson*, page 11, lines 9-19). This teaching would contradict the Examiner's contention since it suggests that the particle size is indeed an important parameter. The Examiner has not offered any evidence to prove otherwise.

In addition, *Dickinson* appears to suggest that lactose particles having small diameters such as those having a diameter of less than 10 microns are undesirable (see, *Dickinson*, col. 10-11, Example H). Thus, a person skilled in the art, following the teachings of *Dickinson*, while would have understood that particle size is an important parameter, would not have been led to including up to 25% of lactose particles that are less than 5 microns in diameter.

Furthermore, Applicant has also provided comparison of examples of the claimed compositions with a representative commercial product, the OXIS TURBUHALER™ (see, e.g., Examples 3 and 4 beginning at page 13). Specifically, both Example 3 and Example 4 demonstrate that the claimed composition exhibits a more consistent delivery of the drug than the commercial product (see, e.g., the specification at page 13 paragraph [0055] and at page 16 paragraph [0057]). Thus, these examples demonstrate that the claimed composition is superior to a representative commercial product.

Therefore, Applicant respectfully submits that *Dickinson* does not render the presently claimed invention obvious. Withdrawal of the § 103(a) rejection over *Dickinson* is respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

Application No.: 10/646,361

Docket No.: TEVNHC 3.0-587

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: November 19, 2007

Respectfully submitted,

By Weining Wang

Weining Wang

Registration No.: 47,164

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PTO/SB/30 (04-07)

Approved for use through 09/30/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Request for Continued Examination (RCE) Transmittal Address to: Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number	10/646,361-Conf. #8629
	Filing Date	August 21, 2003
	First Named Inventor	Xian-Ming Zeng
	Art Unit	1616
	Examiner Name	K. M. George
	Attorney Docket Number	TEVNH C 3.0-587

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

ii. ☐ Other _____

b. ☒ Enclosed

i. ☒ Amendment/Reply

iii. ☒ Information Disclosure Statement (IDS)

ii. ☐ Affidavit(s)/Declaration(s)

iv. ☒ Other Petition for Ext of Time (2 mos), and
Petition to Accept Unintentionally Delayed
Claim for Benefit

2. **Miscellaneous**

a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

b. ☐ Other _____

3. **Fees** The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

a. ☒ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments to Deposit Account No. 12-1095. I have enclosed a duplicate copy of this sheet.

i. ☒ RCE fee required under 37 CFR 1.17(e)

ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)

iii. ☐ Other _____

b. ☐ Check in the amount of \$ _____ enclosed

c. ☐ Payment by credit card (Form PTO-2038 enclosed)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED			
Signature	<u>Weining Wang</u>	Date	June 25, 2007
Name (Print/Type)	Weining Wang	Registration No.	47,164
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			
Dated: June 25, 2007		Signature: <u>Weining Wang</u> (Weining Wang)	



PTO/SB/22 (04-07)

Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2006 (Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)		Docket Number (Optional) TEVNHC 3.0-587	
Application Number 10/646,361-Conf. #8629		Filed August 21, 2003	
For INHALATION COMPOSITIONS			
Art Unit 1616		Examiner K. M. George	
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):			
	Fee	Small Entity Fee	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$ _____
<input checked="" type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$ 450.00
<input type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$ _____
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$ _____
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$ _____
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.			
<input type="checkbox"/> A check in the amount of the fee is enclosed.			
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.			
<input checked="" type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.			
<input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>12-1095</u> . I have enclosed a duplicate copy of this sheet.			
I am the <input type="checkbox"/> applicant/inventor.			
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).			
<input checked="" type="checkbox"/> attorney or agent of record. Registration Number <u>47,164</u>			
<input type="checkbox"/> attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____			
<u>Weining Wang</u> Signature		<u>June 25, 2007</u> Date	
<u>Weining Wang</u> Typed or printed name		<u>(908) 654-5000</u> Telephone Number	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
<input checked="" type="checkbox"/> Total of <u>1</u> forms are submitted.			

06/28/2007 SSITHIB1 00000022 121095 10646361

03 FC:1252 450.00 DA

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: June 25, 2007

Signature: Weining Wang (Weining Wang)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

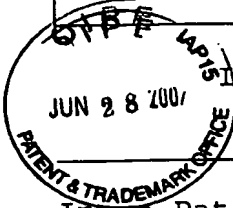
Dated: June 25, 2007

Signature: Weining Wang

(Weining Wang)

Docket No.: TEVNHC 3.0-587

(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Xian-Ming Zeng

Application No.: 10/646,361

Filed: August 21, 2003

For: INHALATION COMPOSITIONS

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: Conf. No.: 8629
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: Group Art Unit: 1616
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: Examiner: K. M. George
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AMENDMENT UNDER 37 C.F.R. 1.114

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed January 25, 2007,
Applicant submits the following amendments and remarks.

AMENDMENTS TO THE SPECIFICATION begin on page 2 of this
paper.

AMENDMENTS TO THE CLAIMS are reflected in the Listing of
Claims which begins on page 3 of this paper.

REMARKS begin on page 7 of this paper.